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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,099	01/24/2002	Fu-Zon Chung	A0000247-01-DRK	1420

28880 7590 03/27/2003

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EXAMINER
LANDSMAN, ROBERT S

ART UNIT	PAPER NUMBER
1647	8

DATE MAILED: 03/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/057,099	CHUNG ET AL.	
	Examiner	Art Unit	
	Robert Landsman	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133)
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/30/02* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *8-15 and 18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,16 and 17* is/are rejected.

7)☒ Claim(s) *7 and 17* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2,3,7* .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

1. Formal Matters

A. Amendment A, filed 12/30/02, has been entered into the record.

B. The Information Disclosure Statement, filed 6/25/02, has been entered into the record.

C. The Information Disclosure Statement, filed 5/7/02, has been entered into the record.

D. The Information Disclosure Statement, filed 3/10/03, has been entered into the record.

E. Claims 1-18 are pending and were subject to restriction in Paper No. 4, mailed 9/30/02. In Amendment A, Applicants elected Group I, claims 1-7, 10, 16 and 17 in part. Since no traversal has been provided, this election will be treated as an election without traverse. Therefore, this restriction is deemed proper and is made FINAL.

2. Information Disclosure Statement

A. The reference to the European Search Report on the IDS filed 3/10/03, has been lined through since this is not a proper citation for an IDS.

3. Claim Objections

A. Claim 1 is objected to since the syntax could be improved by adding "(a)," (b)," etc., before each of the method steps.

B. Claim 7 is objected to since it depends from rejected claim 1, as seen below.

C. Claim 17 is objected to since it depends from claim 15, which is not drawn to a kit. It is believed that claim 17 should depend from claim 16. If this is not the case, then claim 17 will be restricted as not being a part of originally elected Group I.

4. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

A. Claims 1-6, 16 and 17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Applicants are claiming a method of screening for compounds with gabapentinoid activity using an assay which measures Erk-2 activation. It appears to be the intent of this invention to identify compounds which can have the same in vivo effects as gabapentin, such as antiepileptic effects. However, Applicants have provided no guidance or working examples of any compounds other than gabapentin which have the intended in vivo effects, nor have Applicants taught how measuring Erk-2 activiation is indicative of a compound possessing gabapentin activity, as gabapentin is not the only compound which acts via Erk-2 activation. Furthermore, it would not be predictable to one of ordinary skill in the art that a compound which activates Erk-2 would have gabapentin activity since the mechanism of action of gabapentin is unusual, as it would be predicted that most anticonvulsants act via GABA receptors. Therefore, identifying a compound which acts through a distinct, unexpected, pathway to produce anticonvulsant effects would, respectfully, require more than just realizing that the compound activates Erk-2.

Therefore, due to this lack of guidance and working examples of compounds having gabapentin activity which act via Erk-2 activation as well as the inability to predict that compounds, other than gabapentin, which act via Erk-2 would, in fact, have gabapentin activity, leads the Examiner to conclude that undue experimentation would be required to practice the invention as claimed.

B. Furthermore, even if claims 1-6, 16 and 17 were enabled, they would still be limited in scope and would be rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of detecting gabapentinoid activity using mGluR or NK1-expressing cells, does not reasonably provide enablement for detecting gabapentinoid activity in cells which do not express either mGluR or NK1 receptors. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

First, the breadth of claim 1 is excessive. Applicants have disclosed in the specification that gabapentinoid activity can only be measured in cells expressing either mGluR or NK1 receptors and that quisqualate is used to stimulate mGluR and that Substance P is used to stimulate NK1 receptors. However, neither of these receptors is recited in claim 1. Therefore, in the absence of a cell expressing either mGluR or NK1 receptors, Applicants have not taught the artisan how to detect gabapentinoid activity. In other words, Applicants have only provided guidance and working examples of stimulating either mGluR-expressing cells with quisqualate or NK1-expressing cells with Substance P and that only these mGluR or NK1-expressing cells can be used in the present invention to detect gabapentinoid activity. Therefore, it would not be predictable to one of ordinary skill in the art how to measure gabapentinoid activity in the absence of a mGluR or NK1 receptor-expressing cell.

In addition, Applicants state in the sentence bridging pages 6 and 7 that cells respond to gabapentin by inhibiting MAPK signaling pathways *only under certain conditions*. Applicants have not taught what these "certain conditions" are. Therefore, it would not be predictable to one of ordinary skill in the art what conditions to use in order to practice the claimed invention, other than those shown in Examples 1 and 3 of the specification, which use cells expressing either mGLuR or NK1 receptors.

Therefore, in summary, the breadth of the claims is excessive with regard to Applicants claiming a method of detecting gabapentinoid activity using cells which do not express either mGluR or NK1 receptors. Furthermore, there is a lack of guidance and working examples of methods using cells which do not express either mGluR or NK1, nor is it predictable to one of ordinary skill in the art how to practice the claimed invention using cells which do not express either of these receptors. For these reasons, the Examiner has concluded that undue experimentation would be required to practice the invention as claimed.

5. Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A. Claims 1-7, 16 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: transfecting a cell with, or using a cell which expresses either mGluR or NK1 receptors.

In addition, claim 1 does not have a conclusion step which demonstrates that the claimed goal has, in fact, been achieved. The final step of the claim should recite, for example, "wherein an inhibition of Erk2 agonist-mediated phosphorylation demonstrates that the target compound has gabapentinoid activity."

6. Prior Art

A. Though gabapentin was known since 1994 and though screening assays which measure MAPK and Erk-1 activiation were known in the prior art, making a typical screening assay using these signaling cascades either obvious, or taught by the prior art, it appears that Applicants were the first to discover that gabapentin acts via mGluR and NK1 receptor pathways. Therefore, methods of screening compounds using mGLuR or NK1 receptor-expressing systems are novel and unobvious. If this conclusion is incorrect, the Examiner requests a statement to this effect and clarification of Applicants' invention.

7. Conclusion

A. Claims 1-6, 16 and 17 are not allowable.

B. Claim 7 is objected to but would be allowable if rewritten in independent format to include all of the limitations of the base claim.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
March 25, 2003